AUG - 5 2008

510(K) SUMMARY – K080603
(as required by 807.92(c))

Regulatory Correspondent	Regulatory and Marketing Services 962 Allegro Lane Apollo Beach, FL 33572
Submitter of 510(k):	TE ME NA 16, rue des Entrepreneurs Z.I. des Amandiers F-78420 CARRIERES-SUR-SEINE FRANCE 78420 Phone: 011-331-30860530 Fax:
Contact Person:	Wilhelm Waskönig
Date of Summary:	July 23, 2008
Trade/Proprietary Name:	Temena Nerve Location Needles Coated (Hybrid) and Uncoated (USC)
Classification Name:	Anesthesia Conduction Needle
Product Code:	BSP

Intended Use:
The Temena Nerve Location Needles are intended for use in regional anesthesia procedures, by anesthesiologists or other trained professionals, for the location of peripheral nerves with a nerve stimulator and/or with an ultrasound device.

Device Description:
The Temena Hybrid and USC Nerve Location Needles include a stainless steel cannula and connections for anesthetic administration and with the Hybrid Needle a connection for nerve stimulation. The needle is available in a range of lengths and 21 or 22 AWG. The USC (uncoated version) may be used for echo nerve location and the Hybrid (coated version) for both stimulator and echo location.

Predicate Device:
Temena UPC Nerve Stimulator Needle – K990100
Havel Echostim Facit Tip K063380

Substantial Equivalence:
The Temena Hybrid needle is identical to the already cleared Te me na UPC Needle under K990100 with modifications to the coating and surface for use as either echo or stimulation nerve location. Testing has been performed under Design Controls to confirm these changes with acceptable results. Therefore this Te me na hybrid needle is considered to be substantially equivalent.

Te me na 510(k) Device Comparison Chart
Hybrid and USC Needles

Characteristics	Hybrid and USC	Temena K990100	Havel K063380
Nerve Location	Yes	Yes	Yes
Electro Stimulation	Yes	Yes	Yes
Echo Location	Yes	No	Yes
Sizes	21-22 awg	21-30 awg	21 awg
Lengths	35-150mm	25-150mm	40-150mm
Coating	Parylene (Nanolyene)	Teflon	Nanoline
Uncoated Version	Yes	No	Yes
Packaging	Single Teflon Sealed	Same	Same
Sterilization	ETO	ETO	ETO
Regional Anesthesia	Yes	Yes	Yes
Anesthetic Administration Line	Yes	Yes	Yes
Needle Tip	Bevel	Pencil Point (UPA) Bevel (UPC)	Bevel
Coating	Hybrid Yes, USC No	Yes	Yes
Tip Roughness	Yes	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2008

Te Me Na SAS
C/O Mr. Arthur Ward
Regulatory and Marketing Services
RMS Regulatory & Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K080603
Trade/Device Name: Hybrid (Coated) and USC (Uncoated) Nerve Location Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: July 23, 2008
Received: July 28, 2008

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080603

Device Name: Hybrid (Coated) and USC (Uncoated) Nerve Location Needle

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080603